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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,962	12/29/2000	David E. Catcheside	10552.13USC1	2958

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

12

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,962

Applicant(s)

CATCHESIDE, DAVID E.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-36 and 42-69 is/are rejected.
- 7) ☒ Claim(s) 4-7 and 37-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply, filed June 9, 2003 as Paper No. 10, to the previous Office Action. Amendments were not made to the claims.

Claims 1-127 are pending and under consideration in the instant application. It is noted that applicant has indicated in their response that only claims 1-69 are pending; however, there is no specific indication in the response to cancel claims 70-127. Since the claims as indicated are not found to be allowable, claims 70-127 are still pending. Claims 70-127 are withdrawn from consideration as being drawn to an invention non-elected without traverse. Claims 1-69 are ready for examination in the instant application. Any rejection of record in the previous Office Action, mailed December 4, 2002 as Paper No. 9, that is not addressed in this action has been withdrawn.

Acknowledgement is made of applicant's submission of a terminal disclaimer in response to the previous Office Action. The terminal claimer has been considered and entered, and is sufficient to overcome the rejection of claims 1-69 under the judicially created statute of obviousness-type double patenting.

This Office Action only maintains rejections set forth in a previous Office Action, therefore this Office Action is made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-3, 8-36 and 42-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 112

Applicant's arguments filed June 9, 2003 have been fully considered but they are not persuasive. Applicant's arguments are as follows:

1. The specification need not describe all recombination hotspots as the claim limitations only refer to eukaryotic recombination hotspots.
2. The instant claims only represent a modest increase in breadth (of scope) compared to the issued claims of US Patent No. 6,232,112, thus the instant application only seeks to expand the claim coverage to eukaryotic recombination hotspots outside of fungal recombination hotspots.
3. The prior art teaches a large number (approximately 24) of eukaryotic recombination hotspots, presented in the instant specification, to which the skilled artisan can refer for use in the claimed invention. Applicant alleges that these 24 recombination hotspots provide a representative number of recombinational hotspots in sufficient detail such that the skilled artisan could envision the full genus of recombinational hotspots that are claimed.

Applicant's arguments have been fully considered but are not found convincing for the following reasons:

1. The previous Office Action does not state that the specification must describe all recombination hotspots, as suggested in applicant's arguments. Rather, the previous Office Action states that the "specification does not teach how to identify additional 'recombinational hotspots' that can be used in the invention by showing what characteristics are required by describing what elements of a sequence makes it useful as a 'recombinational hotspot'" (see page 4 of the previous Office Action). Even as it regards the eukaryotic recombinational hotspots, applicant has not provided a structure-function relationship for a "eukaryotic recombinational hotspot" so that the skilled artisan could envision what nucleic acid sequences represent a "eukaryotic recombinational hotspot." There is nothing in either the instant specification or the prior art that describes what characteristics of a nucleic acid would make it a "eukaryotic recombinational hotspot", therefore the skilled artisan would not be able to adequately envision a "eukaryotic recombination hotspot" that could be used in the claimed invention.

2. The increase in breadth that applicant claims is modest is in fact very large. Applicant is suggesting that an increase from a fungal recombination hotspot spot to any eukaryotic recombination hotspot is a minor increase; however, this increase includes a huge number of species, each with an unknown number of recombination hotspots. Furthermore, these same limitations were rejected for the same reasons in the previous application which matured into US Patent No. 6,232,112. Thus, the fact that claims of a more narrow scope were issued in a

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previous application is not a substantial argument for the issue of claims that are broader in scope.

3. Applicant's recitation of a number of "eukaryotic recombinational hotspots" in the instant specification and in applicant's arguments does not constitute a written description of a representative number of "eukaryotic recombinational hotspots." There are many reasons for this fact, each of which is discussed below.

First, the number of "eukaryotic recombinational hotspots" is unknown, and it is unclear what nucleotide sequences (henceforth referred to as sequences) constitute a "eukaryotic recombinational hotspots" in any organism. There is no clear consensus sequence that confers a structure-function relationship for a "eukaryotic recombinational hotspots," therefore each individual "eukaryotic recombinational hotspot" must be determined empirically. This is even exemplified by the specific examples that applicant has recited as support for a written description of the claimed genus because there is no consensus sequence among each of these sequences that confers the functional property of a "eukaryotic recombinational hotspot." For example, applicant recites that these sequences can be found in maize, but does not indicate where they are found in maize, what sequences in maize represent a "eukaryotic recombinational hotspot," or what the structure-function relationship is between each of the "eukaryotic recombinational hotspots" that would allow the skilled artisan to envision other sequences that have the functional property of being "eukaryotic recombinational hotspots." The fact that there is no way to envision if any particular sequence is a "eukaryotic recombinational hotspot" and that each sequence representing a "eukaryotic recombinational hotspot" must be determined

empirically indicates that there is no written description of the claimed genus of all “eukaryotic recombinational hotspots.”

The same argument is true of applicant’s recitation of “eukaryotic recombinational hotspots” *near* the gamma globulin loci in humans and chimpanzees (numbers 21 and 22, recited in applicant’s arguments on page 6), *close to* the major histocompatibility locus in mouse (number 20, recited in applicant’s arguments on page 6), *near* the retinoic acid alpha receptor gene in humans (number 23, recited in applicant’s arguments on page 6) or *in the region of* the repeat regions associated with Charcot-Marie-tooth neuropathy (number 24, recited in applicant’s arguments on page 6). First, the recitation of these sequences is vague, as there is no clear indication of what sequences are required to function as “eukaryotic recombinational hotspots,” therefore the skilled artisan could not even envision what individual sequences should be used in the claimed invention. Second, there is no conserved or consensus sequence between each of these sequences that would allow the skilled artisan to envision what other sequences could function as “eukaryotic recombinational hotspots” by virtue of the fact that they contain the conserved or consensus “eukaryotic recombinational hotspot” sequence. Again this indicates that the written description of the claimed genus of all “eukaryotic recombinational hotspots” is insufficient because each sequence purported to satisfy the written description requirement must be determined empirically.

Second, the mere recitation of 24 sequences is not sufficient to describe the claimed genus in this instance. This is especially true in light of the fact that applicant has only recited “eukaryotic recombinational hotspots” from 5 different non-fungal eukaryotes (tomato, maize, fruit fly, mouse and human; see for example page 7 of applicant’s arguments). First, these five

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organisms are not nearly representative of all eukaryotes. Even if, *arguendo*, the indicated organisms were representative of all eukaryotes, the “recombinational hotspots” as recited in applicant’s arguments again have no consensus sequence that functionally describes or links these sequences together as “eukaryotic recombinational hotspots.” Finally, there is no indication that these recombinational hotspots maintain their function as recombinational hotspots across different species, genera or families.

The purpose of reciting a representative number of species to demonstrate a written description for a claimed genus is to demonstrate how to envision other members of the genus by comparison to the specifically recited species. In the instant case, there is no consensus sequence that represents a “eukaryotic recombinational hotspot” in such a manner that the skilled artisan could compare an unknown eukaryotic sequence with a known “eukaryotic recombinational hotspot” and be able to envision that the unknown eukaryotic sequence is a “eukaryotic recombinational hotspot.” Thus, when applicant recites 24 sequences that have no structure-function relationship to each other, as in the instant case, this recitation does not satisfy the written description requirement by reciting a representative number of species within a claimed genus.

In conclusion, in view of applicant’s arguments, it is still determined that the specification has not satisfied the written description requirement for the claimed genus of all “eukaryotic recombinational hotspots.” First, applicant claims that they need not describe all recombination hotspots because the claimed invention only recites the use of “eukaryotic recombinational hotspots.” However, applicant has not even described all “eukaryotic recombinational hotspots,” nor have they provided a structure function relationship for these

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“eukaryotic recombinational hotspots” so that the skilled artisan can envision a sequence that has the function of being a “eukaryotic recombinational hotspot.” Second, applicant claims that the increase in breadth of the claims is minor, but this is not true as set forth above. The increase in the breadth of claims is vast, increasing in size from a single type of eukaryote (fungi) to all known eukaryotes. Finally, applicant suggests that the recitation of approximately 24 putative “eukaryotic recombination hotspots” is a representative number of species of the claimed genus. However, applicant’s alleged representative number of species still does not teach a structure-function relationship for a sequence such that the skilled artisan could envision that sequence as being a “eukaryotic recombinational hotspot.” The fact of the matter is that the skilled artisan cannot envision what constitutes a “eukaryotic recombinational hotspot” from the instant specification or the prior art, thus the written description requirement for the full scope of the claimed invention has not been satisfied.

Allowable Subject Matter

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
AU 1636


DAVID LAMBERTSON
PRIMARY EXAMINER

To whom it may concern,

These papers were in the file, but should have been sent with the Office Action indicated as Paper No. 9. For whatever reason, they were not sent. Please see to it that these papers are sent with this Office Action.

Thank You,

David Lambertson.